

Notice of Allowability

Application No.

10/695,145

Examiner

Melanie Yu

Applicant(s)

GOULD ET AL.

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment with filing of RCE on 16 March 2006.
2. ☒ The allowed claim(s) is/are 1-27.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>15022006</u> . |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date <u>3/06</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Bill Schulman on 27 April 2006.

The application has been amended as follows:

Claim 1, line 8: after "reagent with said mixture", insert --in the second chamber--.

Lines 10-11: "means for holding the test strip prior to contacting the mixture and second reagent combination" has been changed to --means for holding said elongated holder member at a position spaced from the second chamber until said elongated holder member is activated;--.

Claim 9, line 2: "the test strip holds" has been changed to --said elongated holder member-- and "prevent" has been changed to --prevents--.

Line 3: after "second reagent combination" insert --until activated--.

Line 5: "the test strip until said mixture has" has been deleted.

Line 6: "reacted with said second reagent" has been deleted.

Claim 10, line 2: "container" has been changed to --collector--.

Claim 14, line 6: after "reagent to mix", insert --in the second chamber--.

Lines 7-9: "means for holding the test strip prior to said test strip being permitted to be in fluid communication with said test strip sample, said first reagent and said second reagent;" has been changed to --means for holding said elongated holder member at a position spaced from the second chamber until said elongated holder member is activated;--.

Claim 22, line 2: "container" has been changed to --collector--.

REASONS FOR ALLOWANCE

2. The following is an examiner's statement of reasons for allowance: the prior art fails to teach a lateral flow immunoassay device comprising a first chamber containing a first reagent and a second chamber containing a second reagent wherein the first reagent, second reagent and sample mix in the second chamber and an elongated holder member comprising a test strip held at a position spaced from the second chamber until the elongated member is activated. Wickstead et al. (US 6,634,243) teach a first chamber comprising a first buffer reagent and a second chamber, but fail to teach the second chamber comprising a second reagent, and also fail to teach the test strip held at a position spaced from the second chamber. The test strip is connected directly to the second chamber and cannot be activated. Niedbala et al. (US 2003/0064526) teach a first chamber and comprising a first reagent, but fail to teach a second chamber comprising a second reagent and a test strip held at a position from the second chamber. The test strip of Niedbala et al. is connected directly to the first chamber and is not spaced at a position away from the first chamber and cannot be activated. Baldwin et al. (US 2004/0082878) teach an oral fluid collection device comprising a test strip, but fail to teach a first and second chamber comprising a first and second reagent, and also fail to teach a test strip being held at a position spaced away from the second chamber until activation, the test strip is instead connected directly to the sample collector and cannot be activated.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Melanie Yu
Patent Examiner
Art Unit 1641



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

01/30/06